

**Application Number 10/615,336**  
**Amendment dated 29 September 2004**  
**Reply to Office Action of 29 June 2004**

### Remarks

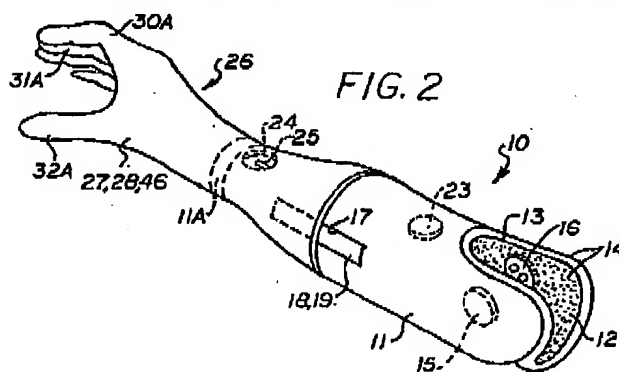
Claims 3, 4, 9, and 17 have been canceled. New Claims 21-24 have been added. Therefore, Claims 1, 2, 5-8, 10-16 and 18-24 are pending in this application.

Applicants thank the Examiner for indicating that Claims 10–15 are allowed, and for indicating that Claims 3, 4, 9, 17 and 18 contain allowable subject matter. Claims 1, 2, 5–7, 19 and 20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,413,611 (“Haslam”). Claims 1, 8, 16 and 19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,888,230 (“Helmy”).

**Claim Rejections Under § 102 based on Haslam.**

Claims 1, 2, 5-7, 19 and 20 stand rejected as being anticipated by Haslam. Claims 1, 19 and 20 are independent; Claims 2 and 5-7 depend from Claim 1.

Haslam discloses a prosthesis apparatus 10 that includes sensor electrodes 15, 16 that detect muscle contractions in the stump. When a muscle in the stump contracts, the electrodes 15, 16 detect an electrical stimulus; the detected signals are then used to control movement of an electromechanical hand frame 27. Thus, the Haslam system is used to control movement of a distal portion of a prosthesis, and is generally not concerned with monitoring physiological or health characteristics of the limb. See generally Haslam 4:55-6:64 and Figure 2, which is reproduced below.



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Claims 1, 2 and 5-7. In contrast to the prosthesis apparatus disclosed in Haslam, amended Claim 1 recites the following:

Claim 1 (currently amended): A socket liner for receiving a limb of an amputee, comprising:  
a liner adapted to receive a limb of an amputee; and  
one or more sensors provided in the liner, the sensors being adapted to ~~monitor~~  
gather physiological data received therein for subsequent monitoring of patient health.

These amendments find support in paragraph [0035] of the originally-filed specification. Haslam does not teach this combination of elements, and therefore, Applicants respectfully submit that Claim 1 is allowable over Haslam. Furthermore, because Claims 2 and 5-7 depend from Claim 1, Applicants submit that Claims 2 and 5-7 are allowable over Haslam for the same reasons that Claim 1 is allowable over Haslam, in addition to reciting further unique distinguishing features. Applicants request that these rejections be withdrawn.

Claim 19. In contrast to the prosthesis apparatus disclosed in Haslam, amended Claim 19 recites the following:

Claim 19 (currently amended): A garment for receiving a limb of an amputee comprising:  
a receiving portion adapted to receive the limb and to hold a plurality of sensors;  
the sensors adapted to receive physiological data from the limb; and  
the garment configured to transmit the physiological data to an end user to monitor the health of the limb.

Haslam does not teach this combination of elements. Specifically, Haslam discloses only sensor electrodes that transmit electrical signals corresponding to muscle contractions to a microprocessor in the limb itself. The microprocessor controls the movements of an electrical hand frame based on the sensed electrical signals. Haslam does not teach transmission of "physiological data to an end user to monitor the health of the limb," as recited in amended Claim 19. Indeed, the Haslam invention is not concerned with the health of the limb.

Based on the foregoing, Applicants submit that Haslam does not teach the elements recited in Claim 19. Therefore, Applicants respectfully submit that Claim 19 is allowable over Haslam, and request that this rejection be withdrawn.

Claim 20. In contrast to the prosthesis apparatus disclosed in Haslam, Claim 20 recites the following:

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Claim 20 (original): A method for monitoring the physiological characteristics of a limb comprising:  
providing a liner having at least one physiological sensor therein; and  
monitoring physiological characteristics of the limb using data accumulated from the sensor.

Haslam does not teach this combination of elements. Specifically, Haslam discloses only using muscle impulse data collected from sensor electrodes to control movement of an electrical hand frame with a microprocessor. The electrical signals detected by the Haslam system are passed directly to the microprocessor. Haslam does not teach "monitoring physiological characteristics of the limb using data accumulated from the sensor." Indeed, the Haslam invention is not concerned with monitoring physiological characteristics of the limb.

Based on the foregoing, Applicants submit that Haslam does not teach the elements recited in Claim 20. Therefore, Applicants respectfully submit that Claim 20 is allowable over Haslam, and request that this rejection be withdrawn.

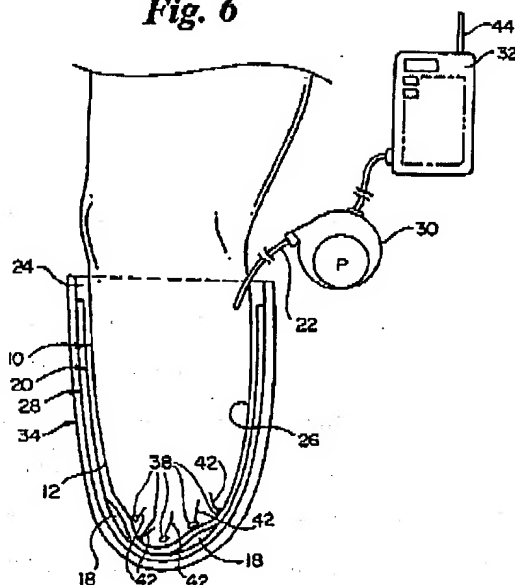
**Claim Rejections Under § 102 based on Helmy.**

Claims 1, 8, 16 and 19 stand rejected as being anticipated by Helmy. Claims 1, 16 and 19 are independent; Claim 8 depends from Claim 1.

Helmy discloses a socket liner that includes pressure-sensitive transducers 38 that are used to measure a reduction in pressure around the stump 10 as a result of loss of volume in the stump 10. The transducers 38 are "placed at locations around the stump 10". The electrical signal generated by the transducers 38 is passed to a microprocessor 32 that controls a vacuum pump 30 configured to adjust the sensed pressure around the stump 10. Specifically, when the transducers 38 detect a reduction in pressure around the stump 10 as a result of volume reduction of the stump, the microprocessor 32 is configured to actuate pump 30 until a desired pressure is reached, at which point microprocessor 32 deactivates the pump 30. In this way, the Helmy system operates as a feedback system to maintain a desired pressure around the stump 10. See generally Helmy 6:35-52 and Figure 6, which is reproduced below.

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**Fig. 6**



**Claims 1 and 8.** In contrast to the prosthesis apparatus disclosed in Helmy, amended Claim 1 recites the following:

Claim 1 (currently amended): A socket liner for receiving a limb of an amputee, comprising:  
 a liner adapted to receive a limb of an amputee; and  
 one or more sensors provided in the liner, the sensors being adapted to ~~monitor~~  
gather physiological data received therein for subsequent monitoring of patient health.

These amendments find support in paragraph [0035] of the originally-filed specification. Haslam does not teach this combination of elements, and therefore, Applicants submit that Claim 1 is allowable over Helmy. Furthermore, because Claim 8 depends from Claim 1, Applicants submit that Claim 8 is allowable over Helmy for the same reasons that Claim 1 is allowable over Helmy, in addition to reciting further unique distinguishing features. Applicants request that these rejections be withdrawn.

**Claim 16.** In contrast to the prosthesis apparatus disclosed in Helmy, Claim 16 recites the following:

Claim 16 (original): A socket liner for receiving a limb of an amputee comprising:  
 a liner for holding a physiological sensor;  
 a physiological sensor configured to receive data from a limb regarding its physiological characteristics;  
 the sensor being in communication with a transmitter;  
 the transmitter configured to send data to a receiver to allow an end user to analyze the physiological characteristics of the limb.

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Helmy does not teach this combination of elements. Specifically, Helmy teaches a liner that includes pressure sensors configured to detect changes in pressure in the region between the liner and a residual limb. In the Helmy system, data from the pressure sensors is sent to a microprocessor that controls a vacuum pump that can be used to adjust the pressure in the region between the liner and the residual limb. In the Helmy system, data from the pressure sensors is not provided "to a receiver to allow an end user to analyze the physiological characteristics of the limb," as recited in Claim 16.

Based on the foregoing, Applicants submit that Helmy does not teach the elements recited in Claim 16. Therefore, Applicants respectfully submit that Claim 16 is allowable over Helmy, and request that this rejection be withdrawn.

Claim 20. In contrast to the prosthesis apparatus disclosed in Haslam, Claim 20 recites the following:

Claim 20 (original): A method for monitoring the physiological characteristics of a limb comprising:  
providing a liner having at least one physiological sensor therein; and  
monitoring physiological characteristics of the limb using data accumulated from the sensor.

Helmy does not teach this combination of elements. As described above, Helmy teaches a liner that includes pressure sensors configured to detect changes in pressure in the region between the liner and a residual limb. In the Helmy system, data from the pressure sensors is sent to a microprocessor that controls a vacuum pump that can be used to adjust the pressure in the region between the liner and the residual limb. Helmy does not teach "monitoring physiological characteristics of the limb using data accumulated from the sensor," as recited in Claim 20. Indeed, the Haslam invention is not concerned with monitoring physiological characteristics of the limb.

Based on the foregoing, Applicants submit that Haslam does not teach the elements recited in Claim 20. Therefore, Applicants respectfully submit that Claim 20 is allowable over Haslam, and request that this rejection be withdrawn.

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**New Claims.**

The examiner has indicated that Claims 3, 4, 9, 17 and 18 contain allowable subject matter. Applicant has cancelled Claims 3, 4, 9 and 17, and has rewritten these claims in independent form including all of the limitations of the base claim and any intervening claims. See new Claims 21-24. Claim 18 has been amended to depend from new Claim 24.

**Conclusion.**

In view of the foregoing amendments, the Applicants submit that this application is in condition for allowance, and respectfully request the same. If, however, some issue remains that the Examiner feels can be addressed by an Examiner's Amendment, the Examiner is cordially invited to call the undersigned for authorization.

Respectfully submitted,

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Dated: 29 Sep 04

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